

IN THE CLAIMS

Please amend the claims as follows:

Claim 1 (Currently Amended): A composition, comprising:

a very low water-soluble drug; and

a porous material;

wherein:

the composition is produced by treating a mixture comprising the very low water-soluble drug and the porous material with a supercritical or subcritical carbon dioxide fluid;

the very low water-soluble drug has a solubility in water at 25 °C of less than 10 µg/mL prior to treatment;

the porous material is not a porous silica material having an average pore diameter of 1 to 20 nm, where a total pore volume of pores having a diameter falling within a range of \pm 40% of the average pore diameter accounts for 60% or more of a volume of all of the pores of the porous material, and having an X-ray diffraction ~~spectrum~~pattern including one or more peaks at a diffraction angle (2θ) corresponding to d of 1 nm or more;

the porous material has an average pore diameter of 1 to 500 nm; and

the porous material has a specific surface area of 100 to 1,800 m²/g.

Claim 2 (Previously Presented): The composition according to claim 1, wherein the porous material comprises a porous carbon material, a porous aluminum material, or a porous silicon material.

Claim 3 (Previously Presented): The composition according to claim 1, wherein the porous material comprises a porous silicon material.

Claim 4 (Previously Presented): The composition according to claim 3, wherein the porous silicon material comprises light anhydrous silicic acid, hydrated silicon dioxide, silicon dioxide, or calcium silicate.

Claims 5-6 (Cancelled).

Claim 7 (Previously Presented): The composition according to any one of claims 1 through 4, wherein the porous material has an average pore diameter of 2 to 200 nm.

Claims 8-9 (Cancelled).

Claim 10 (Previously Presented): The composition according to any one of claims 1 through 4, wherein the porous material has a specific surface area of 200 to 1,500 m²/g.

Claim 11 (Previously Presented): The composition according to any one of claims 1 through 4, wherein a ratio by weight of the very low water-soluble drug to the porous material is 1:0.1 to 1:1,000.

Claim 12 (Previously Presented): The composition according to any one of claims 1 through 4, wherein the very low water-soluble drug is 2-benzyl-5-(4-chlorophenyl)-6-[4-(methylthio)phenyl]-2H-pyridazin-3-one or prednisolone valerate acetate.

Claim 13 (Previously Presented): A drug product comprising the composition according to any one of claims 1 through 4.

Claim 14 (Withdrawn – Currently Amended): A method for producing a the
composition containing a very low water soluble drug as recited in any one of claims 1
through 12 according to claim 1, which method ~~comprises~~ comprising:

placing, ~~in a pressure-resistant vessel~~, a very low water-soluble drug and a porous
material in a pressure-resistant vessel ~~(exclusive of a porous silica material characterized in~~
~~that the material has an average pore diameter of 1 to 20 nm, the total pore volume of the~~
~~material that have a diameter falling within a range of $\pm 40\%$ of the average pore diameter~~
~~account for 60% or more the volume of all the pores of the material, and, when subjected to~~
~~X-ray diffractometry, the material exhibits one or more peaks at a diffraction angle (2θ)~~
~~corresponding to d of 1 nm or more);~~

filling the vessel with carbon dioxide;

maintaining ~~the temperature and pressure in the vessel~~ at a temperature and pressure
such that the carbon dioxide assumes the form of supercritical or subcritical fluid; ~~thereby~~
~~treating the drug and the porous material with the supercritical or subcritical carbon dioxide~~
fluid; and subsequently

discharging the carbon dioxide fluid from the vessel, ~~followed by collection of~~ and
collecting the resultant composition;

wherein:

the porous material is not a porous silica material having an average pore diameter of
1 to 20 nm, where a total pore volume of pores having a diameter falling within a range of \pm
40% of the average pore diameter accounts for 60% or more of a volume of all the pores of
the material, and having an X-ray diffraction pattern including one or more peaks at a
diffraction angle (2θ) corresponding to d of 1 nm or more;

the porous material has an average pore diameter of 1 to 500 nm; and

the porous material has a specific surface area of 100 to 1,800 m²/g.

Claim 15 (Withdrawn – Currently Amended): The method ~~for producing a composition containing a very low water-soluble drug~~ according to claim 14, wherein ~~the a~~ ratio by weight of the very low water-soluble drug to the supercritical or subcritical carbon dioxide fluid is from 1:1 to 1:1,000,000.

Claim 16 (Withdrawn – Currently Amended): The method ~~for producing a composition containing a very low water-soluble drug~~ according to ~~claim 14 or 15~~claim 14, wherein maintaining the vessel comprises maintaining the vessel at the temperature for treatment with the supercritical or subcritical carbon dioxide fluid is of from –40 to 100°C.

Claim 17 (Withdrawn – Currently Amended): The method ~~for producing a composition containing a very low water-soluble drug~~ according to ~~any one of claims 14 through 16~~claim 14, wherein maintaining the vessel comprises maintaining the vessel at the a pressure for treatment with the supercritical or subcritical carbon dioxide fluid is of from 1 to 50 MPa.

Claim 18 (Withdrawn – Currently Amended): The method ~~for producing a composition containing a very low water-soluble drug~~ according to ~~any one of claims 14 through 17~~claim 14, wherein the very low water-soluble drug and porous material are maintained in contact with time for treatment with the supercritical or subcritical carbon dioxide fluid is for a period of from one minute to 24 hours.

Claim 19 (Withdrawn – Currently Amended): ~~The A method for producing a the composition containing a very low water-soluble drug as recited in any one of claims 1 through 12 according to claim 1, which method comprises comprising:~~

~~placing, in a pressure-resistant vessel, a very low water-soluble drug and a porous material in a pressure-resistant vessel (exclusive of a porous silica material characterized in that the material has an average pore diameter of 1 to 20 nm, the total pore volume of the material that have a diameter falling within a range of $\pm 40\%$ of the average pore diameter account for 60% or more the volume of all the pores of the material, and, when subjected to X-ray diffractometry, the material exhibits one or more peaks at a diffraction angle (2θ) corresponding to d of 1 nm or more);~~

~~maintaining the temperature in the vessel at a temperature at which carbon dioxide is in a supercritical or subcritical state;~~

~~filling the vessel with carbon dioxide so as to attain a pressure such that the carbon dioxide assumes the form of a supercritical or subcritical fluid;~~

~~treating the drug and the porous material with the supercritical or subcritical carbon dioxide fluid; and~~

~~subsequently discharging the carbon dioxide fluid from the vessel, followed by collection of and collecting the resultant composition;~~

wherein:

the porous material is not a porous silica material having an average pore diameter of 1 to 20 nm, where a total pore volume of pores having a diameter falling within a range of $\pm 40\%$ of the average pore diameter accounts for 60% or more of a volume of all the pores of the material, and having an X-ray diffraction pattern including one or more peaks at a diffraction angle (2θ) corresponding to d of 1 nm or more;

the porous material has an average pore diameter of 1 to 500 nm; and

the porous material has a specific surface area of 100 to 1,800 m²/g.

Claim 20 (Withdrawn – Currently Amended): The method ~~for producing a composition containing a very low water-soluble drug according to claim 19, wherein the a~~ ratio by weight of the very low water-soluble drug to the supercritical or subcritical carbon dioxide fluid is from 1:1 to 1:1,000,000.

Claim 21 (Withdrawn – Currently Amended): The method ~~for producing a composition containing a very low water-soluble drug according to claim 19 or 20, wherein the temperature for treatment with the supercritical or subcritical carbon dioxide fluid is~~ treating the drug and the porous material comprises treating at a temperature of from -40 to 100°C.

Claim 22 (Withdrawn – Currently Amended): The method ~~for producing a composition containing a very low water-soluble drug according to any one of claims 19 through 21~~ claim 19, wherein the pressure for treatment with the supercritical or subcritical carbon dioxide fluid is treating the drug and the porous material comprises treating at a pressure of from 1 to 50 MPa.

Claim 23 (Withdrawn – Currently Amended): The method ~~for producing a composition containing a very low water-soluble drug according to any one of claims 19 through 22~~ claim 19, wherein the time for treatment with the supercritical or subcritical carbon dioxide fluid is treating the drug and the porous material comprises treating for a period of from one minute to 24 hours.